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| APPLICATION NO.                                     | FILING DATE          | FIRST NAMED INVENTOR          | ATTORNEY DOCKET NO.                   | CONFIRMATION NO. |
|---|----------------------|-------------------------------|---------------------------------------|------------------|
| 10/719,642  | 11/21/2003           | Leon Fernando Garcia-Martinez | 60117-86                              | 3644             |
| 22504 7590 03/21/2007<br>DAVIS WRIGHT TREMAINE, LLP |                      |                               | EXAMINER                              |                  |
| 2600 CENTUR   | Y SQUARE             |                               | BELYAVSKYI, MICHAIL A                 |                  |
| 1501 FOURTH AVENUE<br>SEATTLE, WA 98101-1688        |                      |                               | ART UNIT                              | PAPER NUMBER     |
| ·   |                      |                               | 1644                                  |                  |
|   |                      |                               | · · · · · · · · · · · · · · · · · · · |                  |
| SHORTENED STATUTOR                                  | Y PERIOD OF RESPONSE | MAIL DATE                     | DELIVERY MODE                         |                  |
| 3 MONTHS  |                      | 03/21/2007                    | PAPER                                 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|  | Application No.  | Applicant(s)           |  |  |  |  |
|--|--|------------------------|--|--|--|--|
| Office Action Comments   | 10/719,642   | GARCIA-MARTINEZ ET AL. |  |  |  |  |
| Office Action Summary  | Examiner   | Art Unit               |  |  |  |  |
| 202  | Michail A. Belyavskyi  | 1644                   |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply   | ears on the cover sheet with the c   | orrespondence address  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |                        |  |  |  |  |
| Status   |  |                        |  |  |  |  |
| 1)⊠ Responsive to communication(s) filed on 08 Ja  | nuarv 2007.  |                        |  |  |  |  |
| ·_ ·   | action is non-final.   |                        |  |  |  |  |
| ·—   | , — ,  |                        |  |  |  |  |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |  |                        |  |  |  |  |
| Disposition of Claims  |  |                        |  |  |  |  |
| 4)⊠ Claim(s) <u>1-36</u> is/are pending in the application.  |  |                        |  |  |  |  |
|  | 4a) Of the above claim(s) <u>4-36</u> is/are withdrawn from consideration. |                        |  |  |  |  |
| 5) Claim(s) is/are allowed.  |  |                        |  |  |  |  |
| 6)⊠ Claim(s) <u>1-3</u> is/are rejected.   |  |                        |  |  |  |  |
| 7) Claim(s) is/are objected to.  |  |                        |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or  | election requirement   |                        |  |  |  |  |
| Application Papers   |  |                        |  |  |  |  |
| •  | <i>)</i> *   |                        |  |  |  |  |
| 9) The specification is objected to by the Examiner.   |  |                        |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.  |  |                        |  |  |  |  |
| Applicant may not request that any objection to the c  |  | • •                    |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |  |                        |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |  |                        |  |  |  |  |
| Priority under 35 U.S.C. § 119   |  |                        |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>  |  |                        |  |  |  |  |
| Attachment(s)  | _  |                        |  |  |  |  |
| 1) X Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 4) Interview Summary Paper No(s)/Mail Da                                   |                        |  |  |  |  |
| 2) Notice of Dratisperson's Patent Drawing Review (P10-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date   | 5) Notice of Informal Pa   |                        |  |  |  |  |

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## RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 01/08/07 is acknowledged.

Claims 1-36 are pending.

Claims 4-36 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 1-3 reads on an isolated antibody that can bind to a CD83 polypeptide, wherein said antibody comprises amino acid sequence SEQ ID NO: 26, 28, 33, 37, 41 and 45 are under consideration in the instant application.

2. The filing date of the instant claims is the filing date of the provisional application 60/428,130, i.e. 11/21/02, as the provisional application 60/331,958 fails to provide adequate support under 35 U.S.C. 112 for claims 1-3 of this application.

It is noted that Applicant does not provide any analysis for the support for claimed subject matter in provisional application 60/331,958, as requested in the previous Office Action, mailed on 10/06/06.

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO'9729781 or US Patent 5,766,570, or US Patent 6,068984 each in view of Willuda et al ( J of Biological Chemistry, 2001, Vol.276, pages 14385-14392).

WO''781 teaches an isolated antibody that can bind to a CD83 polypeptide, comprising amino acid sequence that is 100 % identical to the claimed SEQ ID NO:97 (see entire document, Page 4 in particular and sequence alignment).

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US' 570 teaches an isolated antibody that can bind to HB 15. It is noted that said polypeptide is 100% identical to the CD83 polypeptide of SEQ ID NO: 97 of the instant Application. (see sequence alignment.)

US' 984 teaches an isolated antibody that can bind to HB 15. It is noted that said polypeptide is 100% identical to the CD83 polypeptide of SEQ ID NO: 97 of the instant Application.

The claimed invention differs from the reference teaching in that the WO' 781 or US '570 or US '984 does not explicitly teaches multimerized antibody, as recited in the instant claims

Willuda et al., teach that multimerization of antibody has an advantage over monomer form of antibody as a key feature in the design of the optimal targeting molecule (see entire document, Abstract in particular). Willuda et al., teach further teach that the use of multimeric form of antibody (see page 14385 in particular).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of Willuda et al., to those of WO' 781 or US '570 or US '984 to obtain a claimed multimerized antibody that can bind to a CD83 polypeptide of SEQ ID NO:97.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because multimerization of antibody has an advantage over monomer form of antibody as a key feature in the design of the optimal targeting molecule as taught by Willuda et al., and thus can be performed for antibody taught by WO' 781 or US '570 or US '984 to improved their targeting efficacy. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Semaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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5. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable Us Patent Application 10/496,284 in view of Willuda et al (J of Biological Chemistry, 2001, Vol.276, pages 14385-14392).

US' 284 teaches an isolated antibody that can bind to CD83 polypeptide. US' 284 teaches that said antibody comprises the same SEQ ID NOs as claimed in the instant claim 3, i.e. SEQ ID NOs: 26, 28, 33, 37, 41 and 45.

The claimed invention differs from the reference teaching in that the US' 284 does not explicitly teaches multimerized antibody, as recited in the instant claims

Willuda et al., teach that multimerization of antibody has an advantage over monomer form of antibody as a key feature in the design of the optimal targeting molecule (see entire document, Abstract in particular). Willuda et al., teach further teach that the use of multimeric form of antibody (see page 14385 in particular).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of Willuda et al., to those of US' 284 to obtain a claimed multimerized antibody that can bind to a CD83 polypeptide of SEQ ID NO:97.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because multimerization of antibody has an advantage over monomer form of antibody as a key feature in the design of the optimal targeting molecule as taught by Willuda et al., and thus can be performed for antibody taught by US' 284 to improved their targeting efficacy. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Semaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claim 1-3 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-17 of copending Application No. 10/496,284. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 15-17 of copending Application No. 10/496,284 recites an antibody that can bind to a CD83. US'284 teaches that said antibody comprises the same SEQ ID NOs as claimed in the instant claim 3, i.e. SEQ ID NOs: 26, 28, 33, 37, 41, 45, 62 and 64.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted that Applicant indicated that a terminal disclaimer will be filed upon indication of allowable subject matter.

8. No claim is allowed.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 571/273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAIL BELYAVSKYI, PH.D. PATENT EXAMINER

1/17/07